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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/817,330	04/02/2004	Qi Jia	UNI.26	1136

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SWANSON & BRATSCHUN, L.L.C.
8210 SOUTHPARK TERRACE
LITTLETON, CO 80120

EXAMINER	
WINSTON, RANDALL O	

ART UNIT	PAPER NUMBER
1655	

MAIL DATE	DELIVERY MODE
08/07/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/817,330	JIA, QI	
	Examiner	Art Unit	
	Randall Winston	1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 May 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-30,32 and 46-58* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-30,32 and 46-58* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *0207,0507*0807
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgement is made of receipt and entry of the amendment filed on May 9, 2007.

The rejections made under 35 U.S.C. 112, second paragraph, set forth in the previous office action have been overcome by Applicant's amendment.

The rejections made under 35 U.S.C. 112, first paragraph, set forth in the previous office action have been overcome by Applicant's amendment.

Examiner acknowledges that claims 1-18,31 and 34-45 have been cancelled.

Examiner acknowledges that claims 46-58 have been added.

Claims 19-30,32 and 46-58 will be examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 47 and 53 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while enabled for a pharmaceutical composition for the treatment of diseases and conditions, the specification does not enable any person skilled in the art to prepare a pharmaceutical composition for the prevention of diseases and conditions.

The factors to be considered in determining whether undue experimentation is required are summarized in In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) (a) the breadth of the claims; (b) the nature of the invention; © the state of the prior art; (d) the level of one of ordinary skill; (e) the level of predictability in the art; (f) the amount of direction provided by the inventor; (g) the existence of working

examples; and (h) the quantity of experimentation needed to make or use the invention based on the content of the disclosure.

Applicant claims a composition for the prevention of diseases and conditions. Please note the term prevent is an absolute definition which means to stop from occurring and, as such, requires a higher standard for enablement than the instantly disclosed invention. Applicant has only demonstrated in the experiment section on pages 35-50, in Applicant's examples, of the specification a pharmaceutical composition for the treatment of diseases and conditions. Applicant's specification, however, fail to provide guidance and/or working examples whereby applicant prepares a pharmaceutical composition for the prevention of diseases and conditions. Accordingly, it will take undue experimentation without reasonable expectation of success for one of skill in the art to prepare a pharmaceutical composition for the prevention of diseases and conditions.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 19-30,32 and 46-58 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Xu (US 6,083,921) in view of Zhou (US 6,319,523) as set forth in the previous office action.

In Applicant's response on 05/09/2007, Applicant argues Xu does not teach or suggest a pharmaceutical composition comprised of a mixture of Free-B-ring flavonoids and flavans and more specifically Xu does not teach or suggest a composition comprised of at least baicalin and catechin. Nor does Xu teach or suggest a pharmaceutical composition for treatment of diseases and conditions related to the skin which can be topically applied. Furthermore, Applicant maintains Zhou does cure the defects of the Xu reference. Zhou does not teach or suggest a pharmaceutical composition for treatment of diseases and conditions related to the skin which can be topically applied. Therefore, Applicant maintains that this combination of references does not render the claims of the instant invention obvious and respectfully requests that the Examiner reconsider this rejection.

Applicant arguments are not found persuasive because claims 19-30,32 and 46-58 still stand rejected under 35 U.S.C. 103(a) as set forth in examiner's non-final office action of 02/09/2007. Although Applicant argues Xu does not teach or suggest a pharmaceutical composition for treatment of diseases and conditions related to the skin which can be topically applied, it appears to examiner that in column 12 lines 25-32, Xu teaches a topical pharmaceutical composition (i.e. the pharmaceutical composition applied as a cream) comprising baicalin (i.e. baicalin is extracted from *Scutellaria*) and excipients used within a topical pharmaceutical composition used for antibacterial purposes. Furthermore, although Applicant argues Zhou does cure the defects of the Xu reference, the Zhou reference is cited by examiner because Zhou does remedy Xu deficiency. Zhou benefically teaches catechin (i.e. the catechin is extracted from *Acacia*

catechu) contained within a pharmaceutical composition used for antibacterial purposes (see, e.g. abstract, claims, especially claims 1 and 5). Therefore, one of ordinary skill in the art of creating the claimed invention pharmaceutical composition would have been motivated to modify Xu's pharmaceutical composition to include the other active ingredient of catechin as taught in Zhou because the above combined two references would create a topical pharmaceutical composition used for antibacterial purposes. Moreover, as discussed in MPEP Section 2114.06, "it is prima facie obvious to combine two or more compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to used for the same purpose..." . The adjustments of other conventional working conditions (i.e. applicant's examples as demonstrated within the tables of applicant's specification of the adjustment of each active ingredient amount within the claimed topical pharmaceutical composition), is deemed a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Accordingly, the invention as a whole is prima facie obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Please note, the intended use of the above claimed composition (i.e. the pharmaceutical composition to treat various diseases and conditions such as in claim 46) does not patentably distinguish the composition, per se, since such undisclosed use is inherent in the reference composition. In order to be limiting, the intended use must

create a structural difference between the claimed composition and the prior art composition. In the instant case, the intended use does not create a structural difference, thus the intended use is not limiting (see, e.g., MPEP 2112).

Please note that the patentability of a product (i.e. in claims 24-29) does not depend upon the method of production. If the product in a product-by-process claim is the same as or obvious from a product of the prior art, then the claim is unpatentable even though the prior art product was made by a different process" (see, e.g. MPEP 2113).

No claims are allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Randall Winston whose telephone number is 571-272-0972. The examiner can normally be reached on 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CHRISTOPHER R. TATE
PRIMARY EXAMINER